REMARKS

Reconsideration is respectfully requested.

Status of the claims

Applicants elected Group I, claims 1, 2, 11-14, and 20-23 drawn to compounds and pharmaceutical compositions containing them, in response to an earlier restriction requirement, which has been made final. However, because the Examiner has found the subject compounds allowable over the prior art, claims drawn to complex compositions, processes for preparing the compounds, and methods of treatment have been rejoined. Accordingly, claims 1-47 are pending.

Claims 1-4, 11-13, 15, 17-18, 21, 47 have been amended for clarification. Specifically, claim 1 has been amended to clarify what "derivatives" are recited. This amendment finds support in the specification at, for example, page 5, lines 1-6; page 5, line 32 to page 6, line 16; and page 8, lines 8-11. Claim 2 has also been rewritten in independent form and amended for conciseness and to clarify that derivatives of the specific compounds are recited. This amendment is supported in the specification at, for example, page 5, lines 3-6 and 19-20; page 6, lines 8-15; and page 8, lines 18-20. Accordingly, no new matter is added to the application.

Claim Rejections under 35 U.S.C. § 112

A. Claims 1, 3-14, and 24-37 are rejected as allegedly indefinite because claim 1 does not recite the variables n and R_1-R_3, which are recited in dependent claim 2. The Examiner states that "[t]here is insufficient antecedent basis for this limitation in the claim."

Claim 1 recites a compound and certain derivatives, which includes the specific compounds recited in claim 2. *See, e.g.*, specification at page 1, lines 19-21. Claim 2 has been amended to independently recite these specific compounds and their derivatives according to the variables n and R_1, which are recited for the first time in claim 2. The variables do not need any

antecedent basis because they do not refer to a previously recited limitation. Applicants submit that the claims are definite as amended and the rejection should be withdrawn.

B. Claims 1, 3-10, and 24-37 are rejected as indefinite because the term "derivative" is allegedly unclear. The claims have been amended to specify the classes of derivatives referred to in the specification, namely tautomers (*see* page 5, lines 1-2), stereoisomers (*see* page 5, line 33 to page 6, line 2), analogs (*see* page 5, lines 2-7), anhydrides (*see* page 5, lines 1-2), prodrugs (*see* page 8, lines 8-20), and pharmaceutically acceptable salts and solvates (*see* page 6, line 13 to page 8, line 7). Furthermore, the specification provides illustrative examples of the derivatives. *See* pages 5-8. One of ordinary skill in the art would understand the bounds of the claims as amended. Accordingly, it is respectfully requested that the rejection be withdrawn.

C. Claims 15, 16, and 47 are rejected as allegedly failing to comply with the written description requirement. According to the Examiner, the Applicants have failed to demonstrate to one of ordinary skill in the art, as of the filing date, that they were in possession of compositions comprising a compound according to the present invention and a second therapeutic agent. Various classes of the second therapeutic agent include alkylating agents, antimetabolites, vinca alkaloids, antibiotics, cytokines, growth factors, and NSAIDs, such as aspirin.

The Examiner's position is that there is no structure or guidance given to identify specific second therapeutic agents and "[t]he specification does not define the compound[s] in these categories." However, according to the MPEP discussion of the written description requirement, "[t]he description need only describe in detail that which is new or not conventional." MPEP § 2163 II.A.3(a) (citing *Hybritech v. Monoclonal Antibodies*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)); *see also Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art.") (emphasis added). One of ordinary skill in the art would readily identify alkylating agents, antimetabolites, vinca alkaloids, antibiotics, cytokines, growth factors, and NSAIDs that are appropriate for the recited compositions. This is supported by documentary evidence from Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9th ed. (1996) (Exhibit A) and , Basic & Clinical Pharmacology, 9th ed., 537-541

(2004) (Exhibit B), which demonstrate the understanding in the art of the various classes recited and provide examples of therapeutic agents in each.

The Examiner further argues that the classes of second therapeutic agents include functional language, and "functional language recited without any correlation does not meet the written description requirement .... Claims employing functional language as the point of novelty, such as applicants', neither provide those elements required to practice the inventions nor 'inform the public' during the life of the patent of the limits of the monopoly asserted." Even if it were true that the classes of second therapeutic agents included functional language, Applicants' claims do not employ functional language as a point of novelty. Instead, the composition is described using terms well-understood by one of ordinary skill in the art, enabling one to exercise routine skill to select a second therapeutic agent.

Therefore, Applicants have demonstrated possession of the invention as claimed, and thereby satisfied the written description requirement, by "describ[ing] in detail that which is new or not conventional." *See* MPEP § 2163 II.A.3(a). The rejection of claims 15, 16, and 47 should be withdrawn.

D. Claims 14, 17-19, and 38-46 are also rejected as allegedly failing to comply with the written description requirement. The Examiner apparently rejects claim 14 on the grounds that the recited unit dosage range is not described in the specification. The broader unit dosage range recited in claim 14 is supported in the specification at page 8, lines 33-34.

The Examiner also asserts that the specification provides no tests or data to show that the subject compounds are effective in the claimed methods of treatment. However, the specification states, "Tiruchenduramine of the formula 1 was tested for anti-diabetic activity by an *in-vitro* assay and [it] was found that it inhibits α-glucosidase at 78.8 μg." Specification at page 3, lines 2-4.

Furthermore, "[t]here is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed." MPEP § 2163 II.A (*citing In re Wertheim*,

541 F.2d 257, 262 (C.C.P.A. 1976). "Consequently, a rejection of an original claim for lack of written description should be rare." *Id.* The knowledge and level of skill in the art are relevant in determining whether adequate written description exists. *See* MPEP § 2163 I.A (*citing Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996).

The use of α-glucosidase inhibitors to treat diabetic disorders, including effective dosages, is known in the art. *See, e.g.*, Katzung, Basic & Clinical Pharmacology, 9th ed., 710-711 (2004) (Exhibit C). In view of the strong presumption that original claims 17-19 satisfy written description and the level of skill in the art, the disclosure by the applicants that Tiruchenduramine is effective to inhibit α-glucosidase would convey to one of ordinary skill in the art that they were in possession of the claimed invention at the time of filing.

Accordingly, the withdrawal of the present rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is kindly requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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